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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/575,246

12/11/2006

Ge Ming Lui

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EXAMINER

WANG, CHANG YU

ART UNIT

PAPER NUMBER

1649

MAIL DATE

DELIVERY MODE

04/14/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	Application No. 10/575,246	Applicant(s) LUI, GE MING	
	Examiner Chang-Yu Wang	Art Unit 1649	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 06 April 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☐ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: _____.
 Claim(s) objected to: _____.
 Claim(s) rejected: 11-17.
 Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
 12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
 13. ☐ Other: _____.

/C. Y. W./
Examiner, Art Unit 1649

/Christine J Saoud/
Primary Examiner, Art Unit 1647

Continuation of 5. Applicant's reply has overcome the following rejection(s): The rejection of claims 11-17 under 35 U.S.C. 112, second paragraph, as being indefinite.

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's arguments have been fully considered but they are insufficient to overcome the rejection under 102(b) and the rejection under 103(a). The rejections are maintained for the reasons made of record in the office action mailed 1/7/09 for the reasons made of record.

Claims 11-12 and 17 stand rejected under 35 U.S.C. 102 (b) as being anticipated by US Patent No. 5827641 (Parenteau et al. issued on Oct 27, 1998). In particular, Applicant argues that the '641 patent teaches in vitro corneal model and does not teach the corneal biopolymer support containing any growth factor, laminin, fibronectin or RGDS, bFGF- or EGF-conjugated with polycarbophil. Applicant argues that the '641 patent does not teach the support is suitable for transplantation into a damaged cornea.

In contrast, the '641 does the claimed teach incorporation of any attachment reagents to the biopolymer support wherein the support is in the shape of a cornea because the '641 patent teaches an cornea equivalent for cornea transplantation comprising endothelial cells seeded on membranes made of biopolymer including collagen IV and coated with heparin (i.e. heparin sulfate) and heparin-binding growth factor. The biopolymer including collagen IV and coated with heparin and heparin-binding growth factor are bFGF or EGF-conjugated with polycarbophil, which meet the limitation as recited in instant claims 11-12 and 17 (see col.5-7; col. 5, lines 21-60; col. 6, lines 50-65 in particular).

Claims 11-17 stand rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5827641 (Parenteau et al. issued on Oct 27, 1998) in view of US Patent No. 6645715 (Griffith et al. issued on Nov 11, 2003, priority Jan 25, 1999) and US Patent No. 6689165 (issued Feb 10, 2004, priority Mar 31, 2000). In particular, Applicant argues that none of the cited references teach a biopolymer having growth and attachment factors within the biopolymer that is suitable for transplantation into a damaged cornea. Applicant argues that Griffith teaches in vitro, avascular, human corneal equivalent comprising human cell lines not a corneal biopolymer support for transplant into a cornea. Applicant argues that Jacob teaches an ocular device that is designed for growth of corneal epithelial cells on the convex or outside surface of the device.

In response, Applicant cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, the '641 patent teaches an artificial cornea transplant support and an cornea equivalent comprising endothelial cells seeded on membranes made of biopolymer including collagen IV and coated with heparin (i.e. heparin sulfate) and heparin-binding growth factor (i.e. bFGF or EGF-conjugated with polycarbophil). The '641 patent teaches the cornea equivalent (i.e. an artificial cornea transplant) comprising an inner endothelial cell layer, a middle stromal cell-collagen mixture layer and an external epithelial cell layer (see col. 14, claims 1-16; in particular) for cornea transplantation and also teaches the endothelial cells can be derived from different sources including different cornea endothelial cells and non-corneal endothelial cells derived from human (see col. 5, lines 1-5; col. 5, line 61-col. 6, line 41; col. 8, lines 44-67, in particular).

Although the '641 patent does not explicitly teaches the use of human corneal endothelial cells in the corneal transplant as in claims 13 and 14, the '715 patent teaches that corneal endothelial cells in the corneal transplant can be derived from human (see col. 15-16). Although the '641 patent does not teach a half full-thickness as recited in instant claims 14-16 and also fails to teach laminin, RGDS, FGF or EGF-conjugated with polycarbophil as recited in instant claims 11 and 14, the '715 patent teaches artificial cornea transplant supports or artificial cornea transplants with different thickness comprising a base biopolymer with laminin, fibronectin, RGDS, bFGF conjugated with polycarbophil, EGF conjugated with polycarbophil or heparin sulfate seeding human corneal endothelial cells onto the biopolymer as recited in instant claims 11-17 (see col. 19-24). The '715 patent teaches an artificial mammalian cornea comprising an endothelium, a stromal matrix, an epithelium and at least one layer of Bowman's or Descemet's membrane (see col. 19-24; col. 12, lines 18-55; col. 19-22; col 26, claims 1-22). In addition, the '165 patent teaches that different adhesion attachments such as laminin, fibronectin, integrin, RGDS, FGF, EGF, and TGF- β , can be used in a synthetic device for cornea augmentation or replacement to increases corneal epithelium cell adhesion (see abstract; col. 12-19; col. 19-20, claims 1-18, in particular). Thus, It would have been obvious to a skilled artisan to use human corneal endothelial cells and different attachment agents in the artificial cornea transplant/transplant support as disclosed by the '641 patent to make a different thickness or a half full-thickness artificial cornea transplant because human corneal endothelial cells and different attachment agents have been successfully to be used for making a full or half-thickness artificial cornea transplant as taught by the '715 and '165 patents

/CYW/
4/10/09